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AUTHOR Scadden, Lawrence A.
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ABSTRACT

Personal interviews and written correspondence were used to obtain information from 39 officers of companies involved in the manufacture and distribution of rehabilitation-related products, regarding their perceptions of the potential effects of various economic factors and governmental policies. An attempt was made to identify disincentives to industry participation in the field of rehabilitation technology and to discover incentives that might promote increased commercial activity. Findings are reported for the following issues: financing rehabilitation product acquisition; product identification, selection, and evaluation; market data; federal regulations; patent policy; liability insurance; professional training; and federal funding for development and manufacturing activities. Survey results suggest that industry will supply products for disabled people when market demand is present. Company leaders apparently do not consider identification or evaluation of new products to be disincentives to involvement in the rehabilitation market, nor do they consider government regulations and patent policy to be major disincentives. The primary disincentives relate to small market size, the meager financial resources available to disabled customers, and the difficulties encountered in disseminating product information. (JDD)

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REHABILITATION ENGINEERING CENTER

1901 Pennsylvania Avenue N.W., Suite 700, Washington, D.C. 20006 (202) 955-5810 TDD: (202) 955-5836 FAX: (202) 955-5837

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STIMULATING THE MANUFACTURING AND DISTRIBUTION OF REHABILITATION PRODUCTS: ECONOMIC AND POLICY INCENTIVES AND DISINCENTIVES

Lawrence A. Scadden, Ph.D.

September, 1987

Electronic Industries Foundation
Rehabilitation Engineering Center
1901 Pennsylvania Avenue, N. W.
Suite 700
Washington, D. C. 20006

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ABSTRACT

Personal interviews and written correspondence were used to obtain information from a number of officers of companies involved in the manufacturing and distribution of rehabilitation-related products regarding their perceptions of the potential effects of various economic factors and governmental policies. An attempt was made to identify disincentives to industry participation in the field of rehabilitation technology and to discover incentives that might promote increased commercial activity. Findings are reported for the following issues: Financing rehabilitation product acquisition; product identification, selection and evaluation; market data; federal regulations; patent policy; liability insurance; professional training; and federal funding for development and manufacturing activities. Survey results suggest that industry will supply products for disabled people when market demand is present. Company leaders apparently do not consider identification or evaluation of new products to be disincentives to involvement in the rehabilitation market. The primary disincentives relate to small market size, the meager financial resources available to disabled customers and the difficulties encountered in disseminating product information.

INTRODUCTION

The slow diffusion of quality rehabilitation products into common usage by people with disabilities has been a major concern of many groups: industry, rehabilitation professionals, potential users, and even the United States Congress. In 1982,

the Congressional Office of Technology Assessment (OTA) released a report that discussed its conclusions relating to the production, marketing and diffusion of rehabilitation technologies. The report, entitled TECHNOLOGY AND HANDICAPPED PEOPLE, presented a series of options that might be taken by Congress to stimulate the development and diffusion of innovative technology intended to increase the independence, productivity and quality of life for people with disabilities. A significant proportion of these options concerned means to stimulate the involvement and commercial success of industries engaged in the production and distribution of these technologies.

This paper describes findings of a project designed to study basic economic factors and policies that may affect industrial efforts to operate successfully in the rehabilitation product marketplace. This study had, as a secondary goal, the validation of the assumptions and conclusions presented in the OTA report. The investigation took the form of an in-person, in-depth interview with key officers of companies with experience in the manufacturing and distribution of rehabilitation products, a follow-up mail request for comments, and responses to a written report of preliminary findings and recommendations.

BACKGROUND

As an integral part of the Electronic Industries Foundation Rehabilitation Engineering Center's primary mission of investigating strategies that will increase the availability of appropriate rehabilitation technology through commercial channels, research was designed to study the effects of economic issues and public policies upon company decision-making and practices that affect the production and distribution of these products. The study had as one of its goals the investigation of the disincentives to company participation in the field of rehabilitation product manufacturing and distribution. Simultaneously, efforts were made to examine potential incentives that might contribute to the amelioration of these existing disincentives and, when implemented, result in increased industry participation in this market.

METHOD

A list of companies which represented a broad range of rehabilitation and medical manufacturers and distributors was prepared for possible inclusion in an in-person survey. The companies represented diversity on several continua--disability

groups served, size of annual sales, kind and extent of manufacturing capabilities, form of marketing and distribution employed, and degree of third-party payment coverage anticipated. An interview instrument was developed to explore the disincentives perceived by corporate officers that might limit company involvement in the rehabilitation technology market and to elicit comments regarding possible incentives that might remedy existing deterrents to expanded activity. Subsequently, a draft of the results from these interviews was prepared, and the document was circulated to a far larger sample of company officers for reaction and comment.

The following topics were among those addressed in the interview instrument used in this study: type of product line, size of annual sales volume, motivation for entering rehabilitation market, manufacturing capabilities, distribution approaches used, professional organization involvement, identification and selection of new products, product evaluation, marketing strategies, role in professional and user training and equipment service, perceived effects of government regulations (e.g., FDA or FCC), source of marketing data, source of procurement finances, source of research and development funding, perceived role of federal intervention in research and development and/or product engineering funding, perceived role of federal intervention in stimulating the market through financial assistance to end-users for product acquisition, patent policy, effects of liability or other legal issues, perceived role for large companies in the rehabilitation product field, potential effect of increased public relations activities in the rehabilitation technology field, general views on any other major issues and problems relating to corporate involvement with rehabilitation technology. An open-ended interview format was used to encourage an atmosphere of candidness.

The findings reported in this paper are based on interviews with corporate officers from 21 of the original list of companies and mail responses form 18 of the 41 additional company officers solicited by mail. Each participating respondent was either the chief executive officer or designated product or marketing manager. The researchers believe that these 39 companies represent a diverse array of firms involved in the manufacturing and distribution of rehabilitation and medical products. Among the firms surveyed are the nation's largest manufacturers of sensory and communication aids, wheelchairs, ambulatory appliances and aids for daily living. Annual sales for these corporations range between an estimated $500 thousand and $2 billion gross sales and between $250 thousand and $180 million in rehabilitation product sales. The estimated median for annual rehabilitation product sales was between $5 and $10 million. The relatively small number of companies surveyed may

generate tenuous conclusions regarding the perceptions and attitudes of the industry as a whole, but certain trends have emerged that warrant cautious citation in this report.

INTERVIEW RESULTS

Interviewee comments and attitudes appeared to differ widely among the respondents when the discussions concerned either products or practices. Attitudes toward policies, on the other hand, evoked a high degree of concurrence. The following paragraphs summarize the responses from 21 corporate officers interviewed in person. Opinions from mail responses could not be tabulated in the same manner because not all mail responses contained comments on each topic. These responses, however, closely paralleled the views of those interviewed. Key written comments are cited, however, when they reflect strong, divergent views. Other minority opinions are also noted. Ten key topics are reported.

Financing Product Acquisition

As anticipated, high risk and low return on investments were routinely named as being the disincentives to industry participation in the rehabilitation products market. Of the many causes for this risk and low profitability, the limited financial resources available to the end-users of rehabilitation products were identified by more interviewees than any other issue. Seventeen of the 21 persons interviewed placed this item as the foremost disincentive to the release of new products. Two of the remaining four placed this topic as the second most critical issue. These 19 interviewees felt that public sector efforts were needed to stimulate the market by creating improved funding programs for disabled individuals. Limited tax credits, government backed guaranteed loans, low interest loans, and broader third-party payment coverage through vocational rehabilitation, Medicare, Medicaid and private insurance carriers were the most frequently mentioned funding options.

Seventeen of the 21 interviewees addressed each of these funding options to some degree.

When discussing the issue of partial tax credits for end users, several interviewees supported a 50% tax credit with a maximum dollar ceiling. One interviewee felt that tax credits should be limited to products that are to be used in employment.

The issue of Medicare and other sources of third-party payment also elicited numerous additional comments. These were

primarily in the form of advocacy. Four interviewees stated that the current application of "medical necessity" regulations promotes the acquisition of less expensive and, therefore, frequently lower quality products. These devices must be replaced more frequently because they have a shorter unit life cycle. The need to strike a balance between cost containment and human need was universally acknowledged by those interviewed, but recent public efforts tended to be perceived as having been short-sighted.

Further, 15 interviewees stressed that "life enrichment" devices, health and "wellness" devices, as well as "medically necessary" products should be covered by third-party payments. Two interviewees, however, emphasized that assurances must be given to exclude coverage for "convenience" devices. One interviewee added that no company should have products covered unless it could offer training and service support for their products. Finally, one interviewee stated unequivocally that public funding programs should not be used to cover any additional rehabilitation products. A quote from this written response is presented below because the excerpt reflects the opinions of a strong minority of those surveyed.

> "Slow diffusion (of rehabilitation products) is beneficial in the sense of not flooding the market with products that are functionally inferior, inadequate or incomplete; which in turn allows room for new developments and various beneficial improvements... Our need for subsidy will not permit frequent replacements."

Product Identification

Twenty of the 21 companies did not perceive identification of new products to be a problem. Most of the interviewees stated that new ideas and prototypes are brought to the firm regularly for consideration. Developers seek them out. The vast majority of the devices brought for consideration are eventually rejected either because they are not commercially viable or because they do not fit existing product lines.

One interviewee stated that there have been difficulties in dealing with developers because many do not understand that rehabilitation products rarely produce profit. Other developers refuse to permit alterations in designs although the changes might make the product more useful and marketable.

All of the company representatives stated that internal research and development is an ongoing activity. Each believed that the company worked closely with the potential consumer market, both the end-users and the rehabilitation and medical professionals. Thus, they believed that product identification was handled adequately within the company.

Product Selection

Nineteen of the interviewees stated that the two most important criteria used in the selection of new products were: (1) projected return on investment when weighed against anticipated risk, and (2) insuring that the new product fit into existing product lines thus taking advantage of their established strengths in the delivery of product and customer services. Two of the interviewees stated that the selection of new products was based primarily upon the determination that customers would have access to financial resources.

Product Evaluation

All company representatives stated that internal evaluation of new products takes place prior to releasing them into the market. Eight of these companies indicated that the less technically sophisticated aids received only cursory evaluation by a few potential customers, professionals, and dealers. All companies indicated that the "high tech" devices were evaluated by staff with the aid of external consumer and professional assistance.

Seventeen of the interviewees stated that federal funds should not be used for rehabilitation product evaluation unless the task is related to either third-party coverage or to insure human safety. These restrictions were offered for several reasons. First, in the past, such evaluations have not been timely enough to meet the decision-making needs of the companies. Second, these evaluations have emphasized efficacy rather than user acceptance, an approach that could lead to the release of a product lacking commercial viability. Third, this publicly supported effort would be duplicative to regularly scheduled activities of a company seeking valuable products in a small marketplace. Thus, these company representatives again stressed that the limited federal funds available for rehabilitation technology would be better used to stimulate the marketplace rather than for product evaluations.

Three interviewees stated that external technical evaluation would be helpful, but even this evaluation should be conducted in conjunction with the developer to facilitate inclusion of refinements and to permit observations of user acceptance and enthusiasm as well as product performance.

Demographic Data

Each interviewee stated that improved demographic data regarding disability would be helpful, but no company indicated that its absence produced a severe disincentive to participation in this marketplace. Each interviewee felt that his company had a handle on the market size. The difficult and intangible question was how many people might actually buy a specific device. Demographic data represent but one of the many factors needed to answer that question. The interviewees as a group expressed the desire to have demographic data that would indicate potential functional needs and economic status. These data would have direct influence upon decisions relating to the release of specific products.

Four interviewees stated that data regarding the potential market would have been especially valuable at the time product sales first began. Although the information is not systematized, experience in the rehabilitation market has led to the development of an internal knowledge base that permits operation without a reliable national demographic database on disability.

Federal Regulations

None of the interviewees felt that federal regulations under the administration of the FDA or the FCC produced disincentives to involvement in the rehabilitation or medical technology market. Most felt that compliance was not a problem once the agencies were regularly consulted as part of normal procedures. One company, for instance, reported that a product was dropped from consideration early in the company's existence because of the fear of attempting to comply, but subsequent experience eliminated this concern.

Patent Considerations

No company representative considered existing patent policies as presenting a significant disincentive to involvement in the rehabilitation product market. All expressed the belief that patents were important. They would be sought whenever possible, and patented products brought to them for consideration received special attention. Patents were also considered important because they would often increase the time before competition might appear. Further, they can be helpful in dealing with the international market.

On the other hand, patents do not always stand in the way of a company that develops interest in a specific product or market. Some products are released into the market without patents, and others may be redesigned or refined to avoid infringing upon existing patents. Individual patent decisions are based upon probable market competition and perceived consumer demand.

Liability Insurance

Less than half of the respondents reported having major concerns regarding the effects of increasing liability insurance premiums, but those that did placed this issue as the foremost concern in the rehabilitation product market. One written response provides an articulate summary of the views held by this segment of the companies surveyed. Thus, a quotation from this response is presented below.

> "I know of new products that are being introduced in other countries, but not in the U. S.; not because of fears of safety or efficacy of the product, but because of fears of frivolous litigation costs and their effect upon liability insurance costs and availability. I would regard this issue as the major disincentive for introduction of new products and the low diffusion of quality products into common usage."

Each of the companies expressing concerns regarding liability and other legal issues were involved with either durable medical equipment or mobility products. These ten companies were also among the largest firms sampled, based upon gross annual sales volume. Thus, it may be concluded that liability issues and liability insurance premiums do produce disincentives for larger companies and for firms considering participation within this specific portion of the rehabilitation product marketplace.

Professional Training

Seven interviewees listed the issue of professional training as one of the most significant problems confronting the rehabilitation product industry. Professionals involved in the selection and prescription of new products were perceived by the interviewees as frequently lacking the knowledge necessary to promote appropriate new and innovative aids and devices. One individual, for instance, went as far as to say that no effort relating to improving third-party payment coverage was warranted until a systematic mechanism was established to train rehabilitation and medical professionals to select and prescribe appropriate rehabilitation technology.

Development and implementation of curricula relating to rehabilitation technology application is needed for professional academic programs. Further, regular in-service rehabilitation technology training programs must be provided for clinicians and other rehabilitation professionals already in practice. Creative new financial resources may be needed because existing

professional training programs are already supported by these companies, an activity that constitutes a major portion of the companies' marketing budgets.

Federal Funding for Development and Manufacturing Activities

Most of the companies interviewed or responding by mail have had federal R&D funds in the past, but most expressed major concerns over existing grant and contract programs and policies as they affect the development of rehabilitation products by private industry. Seventeen of the 21 company representatives expressed strong reservations with their concerns centered around two points: 1) objective administration of these programs and 2) timeliness of support.

Several interviewees were concerned about the potential isolation of government program staff. Will their knowledge be relevant to current priorities in the rehabilitation technology R&D field? Who, if not these staff, it was asked, could set the criteria for selecting which company or product was to receive support?

Additional concerns were repeatedly offered relating to the placement of restrictions and regulations by funding agencies. Eight interviewees emphasized the desire and the need to hold research findings proprietary. Further, 14 companies expressed concern over the issue of timeliness. The elapsed time between selecting a project area of interest, requesting funds for initial work, and the actual acceptance and granting of an award is too lengthy for a company to keep competitive in a rapidly changing marketplace. Grant and contract procedures relating to private companies should be revised to eliminate this disincentive to using federal R&D funding.

One interviewee went as far as to suggest revision of grant and contract procedures for industry recipients of federal funds so as to reward companies that successfully brought to market a useful product while penalizing those that failed. In such a procedure, the funds would be considered a loan, to be paid back if new products did not emerge.

The issue of federal support for manufacturing was also addressed. Significant differences in opinion were presented.

Fifteen company representatives expressed interest in having access to some federal support for tooling costs, the making of molds, or other initial costs associated with production. Twelve interviewees, however, strongly emphasized that cash awards were not wanted because restrictions could be expected. Rather, special investment tax considerations were

thought to be more appropriate for companies engaged in rehabilitation technology endeavors. Interviewees pointed out that other industries already receive special investment tax credits for other, less human-related activities.

Three of the company representatives, on the other hand, stated that all companies should be treated equally under federal laws and regulations. Thus, these three individuals believed that special federal privileges should not be extended to rehabilitation technology firms, neither for development nor for manufacturing, either through cash awards or tax considerations.

Marketing Issues

Interviewees consistently referred to difficulties relating to reaching potential product users directly with product information. Present confidentiality laws restrict companies from obtaining useful lists of potential customers from other organizations that provide services to those constituencies. As a result, companies must focus their information dissemination efforts on medical and rehabilitation professionals thus increasing reliance upon professional judgment for individual product selection. Interviewees expressed the belief that the ability to reach disabled customers directly with product information would encourage more assertive and perhaps autonomous decision-making among this population.

SUMMARY AND RECOMMENDATIONS

The options presented by OTA in its 1982 report, TECHNOLOGY AND HANDICAPPED PEOPLE, geared to stimulating the diffusion of appropriate rehabilitation technology, can be grouped into those options that address supply-side issues and those concerned with the demand-side of the economic equation. The following summary of research findings and the resulting recommendations will be organized according to this dichotomy.

SUPPLY-SIDE

Product Identification and Evaluation

Findings: Companies apparently do not have difficulty identifying new products. The commercial viability of prototypes brought to manufacturers could be improved if independent and institutional developers worked more closely with these firms earlier in the design and development process. Government supported external prototype or product evaluation does not appear to be an activity that would provide significant incentives

to firms considering further participation in the rehabilitation technology field. Such external evaluations might be helpful in providing third-party payors data needed in decisions regarding extended coverage. Companies, however, are generally ready and willing to conduct evaluations needed to obtain FDA clearances. On the other hand, government sponsored evaluations can be a detriment to timely commercialization or information dissemination.

Recommendation 1. No special federally supported effort to provide liaison between developers and manufacturers appears to be warranted as a potential incentive to industry involvement in this field. Independent developers, however, should have access to materials that will guide them in their efforts to contribute technologically to the needs of disabled people. These materials should describe strategies for identifying and confirming human needs and for locating appropriate manufacturers and distributors.

Recommendation 2. Government supported institutional developers should be encouraged to cooperate closely with firms so as to expedite the transfer of the research findings into commercial products in a timely fashion. Consideration should be given to establishing funding policies that require assurances that industry review and support product R&D efforts that exist or will be obtained within a set period of time. Cost-sharing of advanced product R&D activities is one approach deserving consideration.

Recommendation 3. Government supported product evaluations should be initiated for the purpose of expediting extensions of third-party payment coverage for new products or for insuring human safety. Any other product evaluation projects deemed necessary should be conducted in conjunction with developers to facilitate gathering of data that will result in rapid refinements of commercially viable products.

Effects of Government Regulations and Patent Policy

Findings: Neither FDA nor FCC regulations produce apparent disincentives to industry participation in the rehabilitation technology field. Policies and procedures related to obtaining patents for new products also do not impede progress in the development and diffusion of rehabilitation-related products.

Recommendation 4. No efforts should be made at this time to alter FDA or FCC regulations or governmental patent policy solely for the purpose of stimulating industry involvement in the rehabilitation technology field.

Demographic Data

Findings: Development of a comprehensive demographic database on disability in this country would benefit many groups. Established companies engaged in the manufacturing and distribution of rehabilitation products would benefit from the development of comprehensive demographic data regarding the population of disabled people in this country as they plan expanded R&D and marketing efforts. Individuals and groups considering establishment of new companies might find such a comprehensive database even more valuable. Organizations and individuals engaged in planning the future of rehabilitation service delivery programs, however, would be the primary beneficiaries of such a demographic database.

Recommendation 5. Efforts should be made to establish a comprehensive disability and epidemiology demographic database.

Financial Resources for Private R&D and Production

Findings: Most companies would be interested in having access to governmental R&D funds if problems encountered in the past were remedied. The most serious problem with current grant and contract programs identified in this survey relates to the timeliness of awards. Significant delays between R&D phases cannot be tolerated by private companies attempting to be competitive and to maintain reasonable continuity of staff activities. A second problem area relates to maintaining control over proprietary information gained through R&D efforts.

Rehabilitation product manufacturers differ in attitudes toward governmental assistance for production engineering costs. The majority sampled, however, favor consideration of investment tax credits rather than cash awards.

Recommendation 6. Public funding for rehabilitation product R&D activities of private companies -- such as that authorized by the Small Business Innovation Research Act -- must be revised to provide continuity of company activity by improving the timeliness of awards.

Recommendation 7. Consideration should be given by the U. S. Congress to extending limited investment tax credits to private companies engaged in the manufacturing of "high tech" rehabilitation-related products.

DEMAND-SIDE

Financing Product Acquisition

Findings: The primary disincentives to industry participation in the field of rehabilitation product development,

production, and distribution relate to the limited potential market for new products. The meager financial resources available to the targeted user population is a major contributor to this small market. Establishment and maintenance of a variety of financial assistance programs for these potential customers would provide incentives to companies currently involved in this field and potentially encourage participation by others. These programs would also tend to accelerate the rate of rehabilitation product diffusion and utilization.

Recommendation 8. The National Institute on Disability and Rehabilitation Research (NIDRR) should provide funds for demonstration projects to study the efficacy and cost benefits of loan guarantees conducted in conjunction with commercial lenders.

Recommendation 9. Research and demonstration projects must be conducted to identify and establish improved mechanisms for providing disabled people with low interest loans, price subsidies, and governmental product procurement vouchers.

Recommendation 10. Cost benefits studies are needed to analyze the efficacy of vocational rehabilitation procurement of rehabilitation products when compared with the impact on public maintenance and insurance program budgets.

Information Dissemination

Findings: Companies have serious difficulty in disseminating product information directly to disabled individuals. Participation by the end-users in product selection will increase both demand and utilization of this technology. The inability to locate the potential market -- a negative result of normally beneficial "privacy acts" -- places the burden of selection almost solely upon professional prescribers.

Recommendation 11. Private and public efforts and cooperation are needed to establish a more comprehensive mechanism for disseminating rehabilitation product information directly to disabled individuals. This mechanism should include both written information and means to observe products in operation.

Professional Training

Findings: Rehabilitation and clinical professionals play an important role in the diffusion of rehabilitation products because they serve as primary prescribers of these aids and devices. Adequate diffusion, therefore, will be affected by the level of knowledge regarding the state-of-the-art of the rehabilitation technology field. Companies have found that these

professionals do not have access to quality training programs that are needed by them and by their disabled clients that would enable them to develop and maintain knowledge regarding existing technology.

Recommendation 12. Academic and in-service training programs for rehabilitation and clinical professionals must be developed, administered, and maintained if appropriate rehabilitation products are to be prescribed and utilized.

Liability Issues

Findings: Companies that have medical or mobility-related products have serious concerns over liability insurance and litigation. The cost of liability insurance, and fears regarding the cost of litigation, combine to produce a serious disincentive for these companies for the introduction of new products.

Recommendation 13. Research must be conducted to identify means to lower the risk of frivolous litigation and to encompass the rehabilitation product industry within other efforts underway to control the cost of liability insurance for other industries in this country.

CONCLUSION

The results emerging from this study of the disincentives and potential incentives to industry participation in the production and distribution of rehabilitation indicate that: Industry will supply quality and appropriate products for people with disabilities when financially-based demand is present. Efforts must be made by the public and private sectors to improve the ability of disabled people to acquire the use of modern rehabilitation-related products. These efforts must be directed to improving the flow of information regarding the existence and potentials of these products and of increasing access to the financial resources necessary for product acquisition, training and maintenance. With implementation of these programs, companies will have greater incentives to participate fully in this marketplace.

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Electronic Industries Foundation, 1901 Pennsylvania Avenue, N. W., Suite 700, Washington, D. C. 20006.